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| Customized FORM PTO-1390 | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTORNEY DOCKET NO P06794US00/MP |
| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371 | | | | U.S. APPLICATION NO <i>(if known see 37CFR 1.5)</i> 10/018402 |
| INTERNATIONAL APPLICATION NO. PCT/EP99/04628 | INTERNATIONAL FILING DATE 02 JULY 1999 | PRIORITY DATE CLAIMED | | |
| TITLE OF INVENTION INTERVERTEBRAL IMPLANT | | | | |
| APPLICANT(S) FOR DO/EO/US MARNAY, Thierry et al. | | | | |
| Applicant herewith submits to the US Designated/Elected Office (DO/EO/US) the following items and other information | | | | |
| <input checked="" type="checkbox"/> 1. This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. <input type="checkbox"/> 2. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 USC 371. <input checked="" type="checkbox"/> 3. This express request to begin national examination procedures (35 USC 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 USC 371(b) and PCT Art 22 and 39(1) <input type="checkbox"/> 4. A proper Demand for International Preliminary Examination was made by the 19 th month from the earliest claimed priority date. <input checked="" type="checkbox"/> 5. A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) <input type="checkbox"/> a. is transmitted herewith (required only if not transmitted by the International Bureau). <input checked="" type="checkbox"/> b. has been transmitted by the International Bureau. <input type="checkbox"/> c. is not required, as the application was filed in the United States Receiving Office (RO/US). <input checked="" type="checkbox"/> 6. A translation of the International Application into English (35 U.S.C. 371(c)(2)). <input checked="" type="checkbox"/> 7. Amendments to the claims of the International Appln. under PCT Article 19 (35 USC 371 (c)(3)) <input type="checkbox"/> a. are transmitted herewith (required only if not transmitted by the International Bureau) <input type="checkbox"/> b. have been transmitted by the International Bureau. <input type="checkbox"/> c. have not been made; however, the time limit for making such amendments had NOT expired. <input checked="" type="checkbox"/> d. have not been made and will not be made. <input type="checkbox"/> 8. A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). <input type="checkbox"/> 9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). <input type="checkbox"/> 10. A translation of the annexes to the Int'l Prelim. Exam. Report under PCT Article 36 (35 U.S.C. 371(c)(5)) Items 11. to 20. below concern document(s) or information included: <input type="checkbox"/> 11. An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98. <input type="checkbox"/> 12. An Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included <input checked="" type="checkbox"/> 13. A First preliminary amendment . <input type="checkbox"/> 14. A Second or Subsequent preliminary amendment. <input type="checkbox"/> 15. A substitute specification. <input type="checkbox"/> 16. A change of power of attorney and/or address letter. <input type="checkbox"/> 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 & 35 USC 1.821-825 <input type="checkbox"/> 18. A second copy of the published international application under 35 USC 154(d)(4). <input type="checkbox"/> 19. A second copy of the English translation of the international application under 35 USC 154(d)(4). <input type="checkbox"/> 20. Other items or information: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> A copy of the Notification of Missing Requirements under 35 U.S.C. 371. <input type="checkbox"/> In the event that a petition for extension of time is required to be submitted herewith, and in the event that a separate petition does not accompany this response, applicant hereby petitions under 37 CFR 1.136(a) for an extension of time of as many months as are required to render this submission timely. Any fee is authorized in 17(c) | | | | |
| Date. 19 December 2001 | | | | |

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| U.S. APPLICATION NO. (If known) 10/018402 | | INTERNATIONAL APPLICATION NO. PCT/EP99/04628 | | ATTORNEY DOCKET NO P06794US00/MP | |
| <input checked="" type="checkbox"/> 21. The following fees are submitted: <input checked="" type="checkbox"/> Basic National Fee (37 CFR 1.492 (a) (1)-(5): <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Neither Int'l Prelim. Exam. fee nor Int'l Search fee paid to USPTO <input checked="" type="checkbox"/> Search Report has been prepared by the EPO or JPO <input type="checkbox"/> No Int'l Prelim Ex fee paid to USPTO but Int'l Search fee paid to USPTO <input type="checkbox"/> International preliminary examination fee paid to USPTPO <input type="checkbox"/> Int'l Prelim. Ex. fee paid to USPTO & all claims satisfied PCT Art. 33(1)-(4) </div> <div style="text-align: right;"> \$1040 \$ 890 \$ 740 \$ 710 \$ 100 </div> </div> | | | | | |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent

In re patent application of: MARNAY et al.

Serial No.: NEW APPLICATION

Filed: On even date herewith

For: INTERVERTEBRAL IMPLANT

Examiner:

Art Unit:

Dckt No.: P06794US00/MP

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C.

S I R:

Prior to examination, please amend the above-identified application as follows.

IN THE CLAIMS:

A clean version of the amended claims is provided herewith in **Attachment A**. It will be noted that the amended claims have been amended relative to the previously provided version as shown by the marked up version thereof in **Attachment B** provided herewith.


REMARKS

By this Amendment, the claims have been rewritten to reduce the multiple dependencies.

Further and favorable action is solicited.

Respectfully submitted,

Date: 12/19/01

By: 
Marvin Petry
Registration No. 22752

ATTACHMENT A

Clean Replacement/New Claims (entire set of pending claims)

Following herewith is a clean copy of the entire set of pending claims.

1. (amended) An intervertebral implant, having an upper part that has a support face for a vertebra and a lower part that has a support face for an adjacent vertebra, on each of which parts engagement elements, which are accessible from one side of the intervertebral implant, for a manipulation instrument are disposed, characterized in that the upper part and lower part each have protrusions and recesses aimed at the respectively other part, which are offset laterally from one another in such a way that when the upper part has been brought close to the lower part they mesh with one another; and that the engagement elements on the upper part and on the lower part are each disposed in protrusions of these parts in such a way that the engagement elements of the upper part and lower part are located side by side and at least partly overlap in the direction of the height of the intervertebral implant.
2. (amended) The implant of claim 1, characterized in that the engagement elements are insertion openings for pinlike retaining elements of a manipulation instrument.
3. (amended) The implant of claim 2, characterized in that the insertion openings extend substantially parallel to the support faces.
4. (amended) The implant of claim 1, characterized in that the lower part has a central indentation, opposite the lower support face, which indentation is surrounded by a U-shaped edge.
5. (amended) The implant of claim 4, characterized in that the upper part has a central protrusion that fits substantially in complimentary fashion into the indentation.
6. (amended) The implant of claim 4, characterized in that the engagement elements of the lower part are disposed on the two ends of the U-shaped edge.
7. (amended) The implant of claim 5, characterized in that the engagement elements of the upper part are disposed on the central protrusion of the upper part.

8. (amended) The implant of claim 7, characterized in that the engagement elements of the upper part are disposed near the lateral edges of the central protrusion.

9. (amended) The implant of claim 1, characterized in that the upper part and/or the lower part is embodied in substantially platelike fashion.

10. (amended) The implant of claim 1, characterized in that the lower part and the upper part each have a respective receptacle for a pivot insert.

11. (amended) The implant of claim 10, characterized in that the pivot insert has at least one spherical support face, which engages the correspondingly spherically shaped receptacle.

12. (amended) The implant of claim 11, characterized in that the spherical receptacle is disposed in the central protrusion of the upper part.

13. (amended) The implant of claim 10, characterized in that the central indentation of the lower part forms the receptacle for the pivot insert.

14. (amended) The implant of claim 13, characterized in that the pivot insert can be inserted from the side into the receptacle, which has the engagement elements for a manipulation instrument.

15. (amended) The implant of claim 14, characterized in that the pivot insert is insertable into the receptacle along a guide.

16. (amended) The implant of claim 15, characterized in that the pivot insert is embodied substantially in platelike fashion.

17. (amended) The implant of claim 11, characterized in that the pivot insert substantially completely fills up the central receptacle and with its spherical support face protrudes from the receptacle.

ATTACHMENT B

Marked Up Replacement Claims

Following herewith is a marked up copy of each rewritten claim together with all other pending claims.

1. (amended) An intervertebral implant-(1), having an upper part (2) that has a support face (5) for a vertebra and a lower part (3) that has a support face (13) for an adjacent vertebra, on each of which parts engagement elements-(20, 21, 22, 23), which are accessible from one side of the intervertebral implant, for a manipulation instrument are disposed, characterized in that the upper part (2) and lower part (3) each have protrusions and recesses (10, 19; 16, 17, 9) aimed at the respectively other part, which are offset laterally from one another in such a way that when the upper part (2) has been brought close to the lower part (3) they mesh with one another; and that the engagement elements (22, 23; 20, 21) on the upper part (2) and on the lower part (3) are each disposed in protrusions (10; 16, 17) of these parts in such a way that the engagement elements (22, 23; 20, 21) of the upper part (2) and lower part (3) are located side by side and at least partly overlap in the direction of the height of the intervertebral implant-(1).

2. (amended) The implant of claim 1, characterized in that the engagement elements (20, 21, 22, 23) are insertion openings for pinlike retaining elements of a manipulation instrument.

3. (amended) The implant of claim 2, characterized in that the insertion openings (20, 21, 22, 23) extend substantially parallel to the support faces-(5; 13).

4. (amended) The implant of ~~one of the foregoing claims~~ claim 1, characterized in that the lower part (3) has a central indentation-(19), opposite the lower support face-(13), which indentation is surrounded by a U-shaped edge-(16, 17, 18).

5. (amended) The implant of claim 4, characterized in that the upper part (2) has a central protrusion (40) that fits substantially in complimentary fashion into the indentation-(19).

6. (amended) The implant of ~~one of claims 4 or 5~~ claim 4, characterized in that the engagement elements (20, 21) of the lower part (3) are disposed on the two ends of the U-shaped edge ~~(16, 17, 18)~~.

7. (amended) The implant of ~~one of claims 5 or 6~~, characterized in that the engagement elements (22, 23) of the upper part (2) are disposed on the central protrusion (10) of the upper part ~~(2)~~.

8. (amended) The implant of claim 7, characterized in that the engagement elements (22, 23) of the upper part (2) are disposed near the lateral edges of the central protrusion ~~(10)~~.

9. (amended) The implant of ~~one of the foregoing claims~~ claim 1, characterized in that the upper part (2) and/or the lower part (3) is embodied in substantially platelike fashion.

10. (amended) The implant of ~~one of the foregoing claims~~ claim 1, characterized in that the lower part (3) and the upper part (2) each have a respective receptacle (19; 12) for a pivot insert (4).

11. (amended) The implant of claim 10, characterized in that the pivot insert (4) has at least one spherical support face (25), which engages the correspondingly spherically shaped receptacle ~~(12)~~.

12. (amended) The implant of claim 11, characterized in that the spherical receptacle (12) is disposed in the central protrusion (10) of the upper part ~~(2)~~.

13. (amended) The implant of ~~one of claims 10-12~~ claim 10, characterized in that the central indentation (19) of the lower part (3) forms the receptacle for the pivot insert ~~(4)~~.

14. (amended) The implant of claim 13, characterized in that the pivot insert (4) can be inserted from the side into the receptacle ~~(19)~~, which has the engagement elements (20, 21, 22, 23) for a manipulation instrument.

15. (amended) The implant of claim 14, characterized in that the pivot insert (4) is insertable into the receptacle ~~(19)~~ along a guide ~~(26, 27)~~.

16. (amended) The implant of ~~one of claims 10-15~~ claim 15, characterized in that the pivot insert (4) is embodied substantially in platelike fashion.

17. (amended) The implant of ~~one of claims 11-16~~ claim 11, characterized in that the pivot insert (4) substantially completely fills up the central receptacle (19) and with its spherical support face (25) protrudes from the receptacle (19).



104 Rec'd PCT/PTO 26 MAR 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent

In re patent application of: MARNAY, et al

Serial No.: 10/018,402

Examiner:

Filed: December 19, 2001

Art Unit:

For: INTERVERTEBRAL IMPLANT

Docket #: P06794US00/MP

SECOND PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C.

S I R:

Prior to examination, please amend the above identified patent application as follows.

IN THE CLAIMS

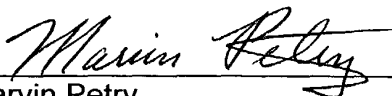
Please add new claims 18-54 as set forth in **Attachment A**.

REMARKS

Applicants are adding new claims in order to more clearly bring out and protect the patentable features of the present invention.

Respectfully submitted,

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March 26, 2002

ATTACHMENT A

New Claims

Following herewith is a clean copy of each new claim.

18. (New) An intervertebral implant comprising:

an upper part which has an upper surface for engaging a vertebrae and a lower surface which has a rounded concave portion,

a lower part which has a lower surface for engaging a vertebrae and an upper surface which comprises a pair of opposed side walls and an opening along one end of the upper surface between the side walls,

an insert having a bottom portion which is shaped to enter the said opening and securely engage said opposed side walls, and a raised portion which is smaller in area, horizontally, than the bottom portion and which projects upwardly from the bottom portion to a convex top which mates with the concave portion of the upper part.

19. (New) An intervertebral implant according to claim 18, wherein at least one of the upper part and lower part have, on its end which includes the opening, engagement means for engaging an instrument for insertion of the upper and lower parts into a space between adjacent vertebrae.

20. (New) An intervertebral implant according to claim 19, the upper part having a downward protrusion which includes the concave portion, said protrusion, in the absence of the insert, being nestable between the opposed side walls of the bottom

part, such that the total height of the upper and lower parts, in the nested condition, without the insert, is less than the additive total height of the upper and lower parts, taken separately.

21. An intervertebral implant according to claim 20, wherein the engagement means comprises instrument receiving apertures on both of the upper and lower parts, and wherein in the nested condition, the apertures of one part overlap vertically with the apertures of the other part.

22. An intervertebral implant according to claim 21, wherein the concave portion and the convex top are spherical.

23. An intervertebral implant according to claim 18, wherein the lower part includes a generally flat surface with three walls including the two said opposed side walls and an end wall located at an end opposite from said opening.

24. An intervertebral implant according to claim 21, including means associated with the lower part for snap fitting the insert into the lower part.

25. An intervertebral implant according to claim 23, wherein said engagement means comprises apertures located in the opposed side walls and opening toward the end where the opening is located.

26. An intervertebral implant according to claim 18, wherein the upper and lower parts are generally rectangular in plan view.

27. An intervertebral implant comprising:
an upper part having an upper surface for engaging a vertebrae and a curved insert receiving bottom surface formed in a downwardly extending protrusion,
a lower part having a lower surface for engaging a vertebrae and a generally flat insert receiving upper surface formed as a recess,
an insert having a curved upper surface for allowing relative movement of the upper and lower parts and located between and engaging the curved bottom surface of the upper part and the generally flat upper surface of the lower part,
the recess in the lower part being defined by raised opposed side walls, and including an opening along one end between the opposed side walls and said insert being insertable onto the upper surface of the lower part laterally through said opening,
and wherein at least one of the upper part and lower part have, at the end thereof where said opening is located, engagement means for engaging an instrument for inserting the upper and lower parts into a space between adjacent vertebrae.

28. An intervertebral implant according to claim 27, wherein the engagement means comprises instrument receiving apertures.

29. An intervertebral implant according to claim 28, wherein the upper part has a downward protrusion which includes the curved insert receiving bottom surface,

said protrusion, in the absence of the insert, being nestable between the opposed side walls of the bottom part, such that the total height of the upper and lower parts, in the nested condition, without the insert, is less than the additive total height of the upper and lower parts, taken separately.

30. An intervertebral implant according to claim 29, including instrument receiving apertures on both of the upper and lower parts, and wherein in the nested condition, the said instrument receiving apertures of one part overlap vertically with the instrument receiving apertures of the other part.

31. An intervertebral implant according to claim 28, wherein the insert includes a generally rectangular lower portion which substantially fills the space formed between the opposed side walls of the lower part.

32. An intervertebral implant according to claim 31, wherein the insert has a raised projection, the curved upper surface of the insert being formed at the top of the projection and being spherical, and the curved insert receiving bottom surface of the upper part being concave and spherical.

33. An intervertebral implant comprising:
an upper part having an upper surface for engaging a vertebrae and having a lower surface having a downwardly extending protrusion which is adapted to receive the top of an insert,

a lower part having a lower surface for engaging a vertebrae and an upper surface formed as a recess and adapted to receive the bottom of an insert,

and wherein the protrusion of the upper part is nestable in the recess of the lower part for initial insertion of the two parts together into an intervertebral space.

34. An intervertebral implant according to claim 33, including engagement means in at least one of the upper and lower parts for engagement with an instrument for inserting the upper and lower parts into a space between adjacent vertebrae.

35. An intervertebral implant according to claim 34, wherein the recess of the lower part includes two opposed side walls, a connecting end wall and an opening along an end opposite from the end wall, and wherein the engagement means comprises openings in the ends of the upper and lower parts at the end of the implant where the opening is located.

36. An intervertebral implant according to claim 35, wherein, in the nested condition, without the insert, the height of the upper and lower parts is less than the additive total height of the upper and lower parts, taken separately.

37. An intervertebral implant according to claim 33, including an insert engagable within the recess of the lower part, said insert having a top with a convex portion, and wherein the lower surface of the upper part has a concave portion shaped to mate with the top of the insert.

38. An intervertebral implant according to claim 37, wherein both the convex top of the insert and the concave portion of the upper part are spherical.

39. An intervertebral implant comprising:
an upper part having an upper surface for engaging a vertebrae and having an insert receiving bottom surface formed in a downwardly extending protrusion,
a lower part having a lower surface for engaging a vertebrae and an insert receiving upper surface comprising opposed side walls which form a recess, wherein without the insert, the protrusion nests within the recess, and
engagement apertures formed at least in the protrusion of the upper part and in the opposed side walls of the lower part for receiving an instrument for inserting the upper and lower parts into a space between adjacent vertebrae, wherein in the nested condition of the upper and lower parts, the engagement openings of the upper and lower parts overlap in the vertical direction.

40. An intervertebral implant according to claim 39, wherein the height of the upper and lower parts, in the nested condition, is less than the additive height of the upper and lower parts, taken separately.

41. An intervertebral implant according to claim 39, including an insert engagable within the recess of the lower part and having a top which has a convex

portion which is engagable with a concave portion in the bottom surface of the downwardly extending protrusion of the upper part.

42. An intervertebral implant according to claim 41, wherein said convex portion and concave portion are spherical.

43. An intervertebral implant comprising:
a generally rectangular upper part having an upper surface for engaging a vertebrae and a curved lower surface for engaging an insert,
a generally rectangular lower part having a lower surface for engaging a vertebrae and a generally flat upper surface for engaging an insert, the upper surface of the lower part having a recess defined by two opposed side walls and an end wall, and including an opening at the end opposite from the end wall,
the insert having a curved upper surface and being insertable horizontally through said opening into the recess for operative engagement of its curved upper surface with the curved lower surface of the upper part.

44. An intervertebral implant according to claim 43, the insert comprising a generally rectangular bottom portion securable by at least said opposed side walls and a top portion projecting upwardly from the bottom portion and of a smaller area, taken horizontally, than the bottom portion.

45. An intervertebral implant according to claim 44, the top of the top portion being convex and the lower surface of the upper part being concave and shaped to mate with the curvature of the top of the insert.

46. An intervertebral implant according to claim 45, wherein the top of the insert and the concave portion of the upper part are spherical.

47. An intervertebral implant according to claim 46, including engagement means in at least one of the upper or lower parts, on the side thereof where the opening is located, for engaging with an instrument for inserting the upper and lower parts into a space between adjacent vertebrae.

48. An intervertebral implant according to claim 43, including means for snap fitting the insert into place on the lower part.

49. An intervertebral implant comprising,
an upper part having an upper surface for engaging a vertebrae and a lower surface for engaging an insert,
a lower part having a lower surface for engaging a vertebrae and an upper surface for securing an insert,
an insert located between the upper and lower parts,

at least one of the upper part and lower part having engaging means for engaging instruments for insertion of the upper part and lower part together into an intervertebral space between two adjacent vertebrae,

the upper part and lower part each having a lead end which leads as the implant is inserted into the intervertebral space and a trailing end opposite the lead end, and said engaging means being located only on the trailing end of the at least one upper and lower part such that insertion instruments may be located only in a working space between parallel lines defined by opposed sides of the implant, and

the lower part having an opening located within the working space for allowing insertion movement of the insert into the space between the upper and lower parts.

50. An intervertebral implant according to claim 49, wherein the engaging means comprise apertures in the trailing end of at least one of the upper and lower parts.

51. An intervertebral implant according to claim 50, including said apertures in both of the upper and lower parts.

52. An intervertebral implant according to claim 49, wherein the upper and lower parts are generally rectangular in plan view.

53. An intervertebral implant comprising,

an upper part having an upper surface for engaging a vertebrae and a lower surface for engaging an insert,

a lower part having a lower surface for engaging a vertebrae and an upper surface for securing an insert,

the upper part and lower part each having a lead end which leads as the implant is inserted into the intervertebral space and a trailing end opposite the lead end and including two lateral sides,

a single anchor on each of the upper surface of the upper part and the lower surface of the lower part, each anchor being located along a line midway between said lateral sides and of a height sufficient to anchor its respective part into a groove cut into the vertebrae which that surface engages, and the anchors having teeth on the tops thereof to prevent their removal from their respective grooves.

54. An intervertebral implant comprising:

an upper part having an upper surface for engaging a vertebrae and a curved insert receiving bottom surface,

a lower part having a lower surface for engaging a vertebrae and an insert receiving upper surface,

an insert having a curved upper surface for allowing relative movement of the upper and lower parts and located between and engaging the curved bottom surface of the upper part and the insert receiving upper surface of the lower part,

the insert receiving upper surface of the lower part being defined by raised opposed side walls, and including an opening along one end between the opposed side walls and said insert being insertable onto the upper surface of the lower part laterally through said opening,

the insert receiving upper surface including a detent recess with an edge extending across the insert receiving upper surface generally perpendicular to the opposed side walls, and said insert having a downward protrusion extending across the insert parallel to the edge of the detent recess, which downward protrusion is resiliently engagable in the detent recess.

INTERVERTEBRAL IMPLANT

5 The invention relates to an intervertebral implant, having an upper part that has a support face for a vertebra and a lower part that has a support face for an adjacent vertebra, on each of which parts engagement elements, which are accessible from one side of the intervertebral implant, for a manipulation instrument are disposed, in order to minimize the structural height of the intervertebral implant upon insertion into an intervertebral space.

10 One such intervertebral implant is known for instance from U.S. Patent 5,314,477. This intervertebral implant is used to replace a disk removed from the intervertebral space, and accordingly the intervertebral implant must have a relatively low structural height, since it has to fit into
15 the gap between vertebrae. This is particularly difficult if an additional pivot insert is also embedded between the upper part and the lower part, as is the case in the known intervertebral implant of U.S. Patent 5,314,477.

20 But even in two-piece intervertebral implants, difficulties also arise, especially if the implants also have pins and other protrusions on their support faces that are intended for anchoring the intervertebral implant in the bone. Often, these parts can be inserted only by widening the intervertebral space greatly. Not only is this
25 difficult, but it also presents the risk of injuries.

Since the intervertebral space has a relatively low height, it is also difficult for engagement elements that a manipulation instrument can engage to be secured to both parts of the intervertebral implant. It is conventional to

have such manipulation instruments engage the upper part and the lower part separately, for instance by means of pins that are inserted into bores on the upper part and lower part, so that with the manipulation instrument, the two parts of the intervertebral implant can be inserted into the intervertebral space and can optionally also be varied in terms of their spacing from one another, thereby allowing a certain spreading open of the intervertebral space. In this respect, reference is made to the pincerlike manipulation instrument of U.S. Patent 5,314,477.

Because of the strong forces, it is necessary to provide a certain structural height for the engagement elements; for instance, the receiving bores must have a certain diameter. This dictates a minimum structural height for the upper part and for the lower part, and in conventional intervertebral implants, the structural heights of the upper part and lower part are thus added together, so that even if the upper and lower parts rest directly on one another, a relatively great structural height of the intervertebral implant is still unavoidable.

It is the object of the invention to embody an intervertebral implant of this generic type in such a way that the minimum structural height is reduced, to make it easier to insert the intervertebral implant into the intervertebral space.

In an intervertebral implant of the type described at the outset, this object is attained in accordance with the invention in that it is proposed that the upper part and lower part each have protrusions and recesses aimed at the respectively other part, which are offset laterally from one another in such a way that when the upper part has been

brought close to the lower part they mesh with one another;
and that the engagement elements on the upper part and on the
lower part are each disposed in protrusions of these parts in
such a way that the engagement elements of the upper part and
5 lower part are located side by side and at least partly
overlap in the direction of the height of the intervertebral
implant.

In such an embodiment, a minimal structural height of
the two intervertebral implant parts resting on one another
10 can be attained, since the engagement elements, which cannot
fall below a minimal structural height, are each disposed in
protrusions of the upper part and lower part, or in other
words in the parts of the upper part and lower part that have
the greatest structural height. These regions of great
15 structural height are embodied as protrusions, next to which
are respective recesses, into which the protrusions of the
respectively other part can dip. As a result, on the one
hand, the engagement elements for the manipulation
instruments are located side by side, and on the other, they
20 can at least partly overlap, so that the total structural
height of the parts resting on one another of the
intervertebral implant can be reduced markedly compared to
conventional intervertebral implants. The result is
accordingly an internested arrangement of the upper and lower
25 parts, with maximal exploitation of the available material
height.

It is favorable if the engagement elements are
insertion openings for pinlike retaining elements of a
manipulation instrument; because of the described
30 construction, these insertion openings can have a relatively
large diameter and can thus receive strong retaining pins,
and nevertheless a relatively low structural height of the

It is advantageous if the insertion openings extend substantially parallel to the support faces; once again, this prevents an increase in the structural height of the intervertebral implant parts.

In a preferred embodiment, it is provided that the lower part has a central indentation, opposite the lower support face, which indentation is surrounded by a U-shaped edge. Thus with the lower part and upper part resting directly on one another, the indentation serves to receive a protrusion on the upper part.

It is advantageous if the upper part has a central protrusion that fits substantially in complimentary fashion into the indentation; that is, the total volume of the indentation is utilized for the protrusion.

It is also advantageous if the engagement elements of the lower part are disposed on the two ends of the U-shaped edge, or in other words are located on the outside.

Conversely, the engagement elements of the upper part can be disposed on the central protrusion of the upper part, or in other words are located farther inward than the engagement elements of the upper part.

In particular, the engagement elements of the upper part can be disposed near the lateral edges of the central protrusion, so that for the upper part as well, the spacing of the engagement elements can be selected to be relatively great; as a result, both the upper part and the lower part

can be reliably secured against skewing.

It should already be noted here that the words "lower part" and "upper part" do not necessarily say anything about the installed position of the intervertebral implant in the spinal column; the part called the "lower part" could in fact be above in the spinal column. What is essential is merely that the upper part and lower part define the intervertebral implant on opposite sides of the implant.

It is especially advantageous if the upper part and/or the lower part is embodied in substantially platelike fashion; these parts naturally, in accordance with the design of the invention, have protrusions and recesses that are oriented toward the respectively other part. The platelike embodiment, however, leads as a whole to a very low structural height of the intervertebral implant.

In a preferred embodiment, the lower part and the upper part each have a respective receptacle for a pivot insert. This pivot insert, which is placed between the upper part and lower part after the insertion of the intervertebral implant, supports the upper part and lower part against one another; it takes on a resilient function, for instance, and furthermore leads to a certain pivotability of the two parts of an intervertebral implant relative to one another, so that a pivotability of the adjacent vertebra is thus attainable as well.

In particular, it is advantageous if the pivot insert has at least one spherical support face, which engages the correspondingly spherically shaped receptacle.

It is favorable if the spherical receptacle is disposed

It is also advantageous if the central indentation of the lower part forms the receptacle for the pivot insert.

According to a preferred embodiment of the invention, it is provided that the pivot insert can be inserted from the side into the receptacle, which has the engagement elements for a manipulation instrument. This is the side from which the upper part and lower part are introduced into the intervertebral space, and it is also from this side that the pivot insert can then be thrust between the already-inserted parts of the intervertebral implant.

It is favorable if the pivot insert is insertable into the receptacle along a guide.

In that the insert as well is preferably embodied
15 substantially in platelike fashion.

An especially favorable design is obtained if the insert substantially completely fills up the central receptacle and with its spherical support face protrudes from the receptacle.

20 The ensuing description of preferred embodiments of the
invention serves in conjunction with the drawing to provide
further explanation. Shown are:

Fig. 1: a perspective exploded view of an intervertebral implant with an upper part, a lower part, and a pivot insert that can be inserted between them;

Fig. 2: a perspective exploded view of the upper part

and the lower part of the intervertebral implant, without an inserted pivot insert;

Fig. 3: a view similar to Fig. 2 with the pivot insert inserted into the lower part;

5 Fig. 4: a perspective view of the upper part and the lower part of the intervertebral implant with maximum mutual proximity;

Fig. 5: a front view of the intervertebral implant of Fig. 4;

10 Fig. 6: a perspective view of the intervertebral implant with the pivot insert inserted; and

Fig. 7: a cross-sectional view of the intervertebral implant of Fig. 6.

15 The intervertebral implant 1 shown in the drawing includes three parts, namely a platelike upper part 2, a platelike lower part 3, and a substantially platelike pivot insert 4.

20 The upper part 2 is embodied flat on its top, thus creating a support face 5, on which various kinds of protrusions 6, 7 are disposed which serve the purpose of anchoring the upper part 2 in a vertebra that rests, with its end face toward an intervertebral space, on the support face 5.

25 The upper part 2 is substantially rectangular in cross section; in the exemplary embodiment shown, a longitudinal edge 8 curves outward.

- 8 -

The dimensions are selected such that the various
5 recesses are essentially filled completely by the protrusions
dipping into them.

Blind bores 20 and 21 are machined into the two legs 16 and 17 of the lower part 3, extending parallel to these legs 16, 17 from their free ends; the diameter of these bores is relatively great in proportion to the height of the legs 16, 17, and this diameter is in fact greater than the thickness or height of the lower part 3 in the region of the central indentation 19.

Blind bores 22 and 23, which extend parallel to the
15 blind bores 20 and 21 in the lower part 3, are machined into
the central protrusion 10 of the upper part 2, in the
vicinity of its side edges. These blind bores 22 and 23
again have a relatively great diameter, which corresponds to
a substantial portion of the height of the protrusion 10 and
20 is greater than the thickness of the upper part 2 in the
region of the recesses 9.

When the upper part 2 and lower part 3 rest tightly against one another in the manner described, the blind bores 20 and 21 of the lower part 3 and the blind bores 22 and 23 of the upper part 2 overlap at least partly in the direction of the height of the intervertebral implant 1, as is clearly shown in Figs. 4 and 5.

The blind bores 20, 21, 22 and 23 serve as receptacles for pinlike extensions of a manipulation instrument, not

shown in the drawing, and thus form engagement elements for this manipulation instrument, which in this way separately engages the upper part 2 and the lower part 3. With this manipulation instrument, it is possible to introduce the upper part 2 and the lower part 3 of the intervertebral implant 1 into an intervertebral space; the very low structural height of the intervertebral implant 1 facilitates this introduction, which can be done essentially without major widening of the intervertebral space.

After the introduction of the upper part 2 and lower part 3 in this way, the two parts of the intervertebral implant 1 can be spread apart; that is, their spacing is increased, for instance with the aid of the manipulation instrument that is holding the upper 2 and the lower part 3.

In this spread-open position of the upper part 2 and lower part 3, it is possible to thrust the pivot insert 4 between the upper part 2 and the lower part 3.

This pivot insert is constructed essentially in the shape of a plate, which has a flat underside 24 and a spherically upward-curved top side 25. The outer dimensions of the platelike pivot insert correspond to those of the central indentation 19 in the lower part 3, so that the pivot insert 4 can be thrust into this indentation, filling it up, specifically from the side toward which the blind bores 20, 21, 22, 23 open. Guide strips 26 on the side edges of the pivot insert 4 engage corresponding guide grooves 27 in the legs 16, 17, so that an insertion guide for the pivot insert 4 is formed that fixes it in the lower part 3 after its insertion. The inserted pivot insert 4, after insertion, fills up the indentation 19 and protrudes with its spherically curved top side 25 upward past the top side of

the lower part 3; the spherical top side 25 dips in
complimentary fashion into the spherically curved indentation
12 on the underside of the protrusion 10, where with the
upper part 2 it forms a ball joint, which enables a certain
5 pivotability of the upper part 2 relative to the lower part 3
(Fig. 7).

The pivot insert 4 can have a detent protrusion 28 on
its flat underside 24; when the pivot insert 4 is inserted
into the lower part 3, this protrusion locks elastically into
10 a detent recess 29 that is located on the bottom of the
indentation 19; as a result, the pivot insert 4 is also fixed
in the insertion direction in the indentation 19.

The upper part 2 and lower part 3 are preferably made
of physiologically safe metal, such as titanium, while the
15 pivot insert 4 preferably comprises a likewise
physiologically safe plastic material, such as polyethylene.
These support faces 5 and 13 can be embodied in an especially
bone-compatible way; for instance, this surface can be
roughened by a coating, so that optimal anchoring to the
20 adjacent bone material is obtained.

CLAIMS

1. An intervertebral implant (1), having an upper part (2) that has a support face (5) for a vertebra and a lower part (3) that has a support face (13) for an adjacent vertebra, on each of which parts engagement elements (20, 21, 22, 23), which are accessible from one side of the intervertebral implant, for a manipulation instrument are disposed, characterized in that the upper part (2) and lower part (3) each have protrusions and recesses (10, 19; 16, 17, 9) aimed at the respectively other part, which are offset laterally from one another in such a way that when the upper part (2) has been brought close to the lower part (3) they mesh with one another; and that the engagement elements (22, 23; 20, 21) on the upper part (2) and on the lower part (3) are each disposed in protrusions (10; 16, 17) of these parts in such a way that the engagement elements (22, 23; 20, 21) of the upper part (2) and lower part (3) are located side by side and at least partly overlap in the direction of the height of the intervertebral implant (1).

2. The implant of claim 1, characterized in that the engagement elements (20, 21, 22, 23) are insertion openings for pinlike retaining elements of a manipulation instrument.

3. The implant of claim 2, characterized in that the insertion openings (20, 21, 22, 23) extend substantially parallel to the support faces (5; 13).

4. The implant of one of the foregoing claims, characterized in that the lower part (3) has a central indentation (19), opposite the lower support face (13), which indentation is surrounded by a U-shaped edge (16, 17, 18).

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5. The implant of claim 4, characterized in that the upper part (2) has a central protrusion (10) that fits substantially in complimentary fashion into the indentation (19).

6. The implant of one of claims 4 or 5, characterized in that the engagement elements (20, 21) of the lower part (3) are disposed on the two ends of the U-shaped edge (16, 17, 18).

7. The implant of one of claims 5 or 6, characterized in that the engagement elements (22, 23) of the upper part (2) are disposed on the central protrusion (10) of the upper part (2).

8. The implant of claim 7, characterized in that the engagement elements (22, 23) of the upper part (2) are disposed near the lateral edges of the central protrusion (10).

9. The implant of one of the foregoing claims, characterized in that the upper part (2) and/or the lower part (3) is embodied in substantially platelike fashion.

10. The implant of one of the foregoing claims, characterized in that the lower part (3) and the upper part (2) each have a respective receptacle (19; 12) for a pivot insert (4).

11. The implant of claim 10, characterized in that the pivot insert (4) has at least one spherical support face (25), which engages the correspondingly spherically shaped receptacle (12).

12. The implant of claim 11, characterized in that the spherical receptacle (12) is disposed in the central protrusion (10) of the upper part (2).

13. The implant of one of claims 10-12, characterized in that the central indentation (19) of the lower part (3) forms the receptacle for the pivot insert (4).

14. The implant of claim 13, characterized in that the pivot insert (4) can be inserted from the side into the receptacle (19), which has the engagement elements (20, 21, 22, 23) for a manipulation instrument.

15. The implant of claim 14, characterized in that the pivot insert (4) is insertable into the receptacle (19) along a guide (26, 27).

16. The implant of one of claims 10-15, characterized in that the pivot insert (4) is embodied substantially in platelike fashion.

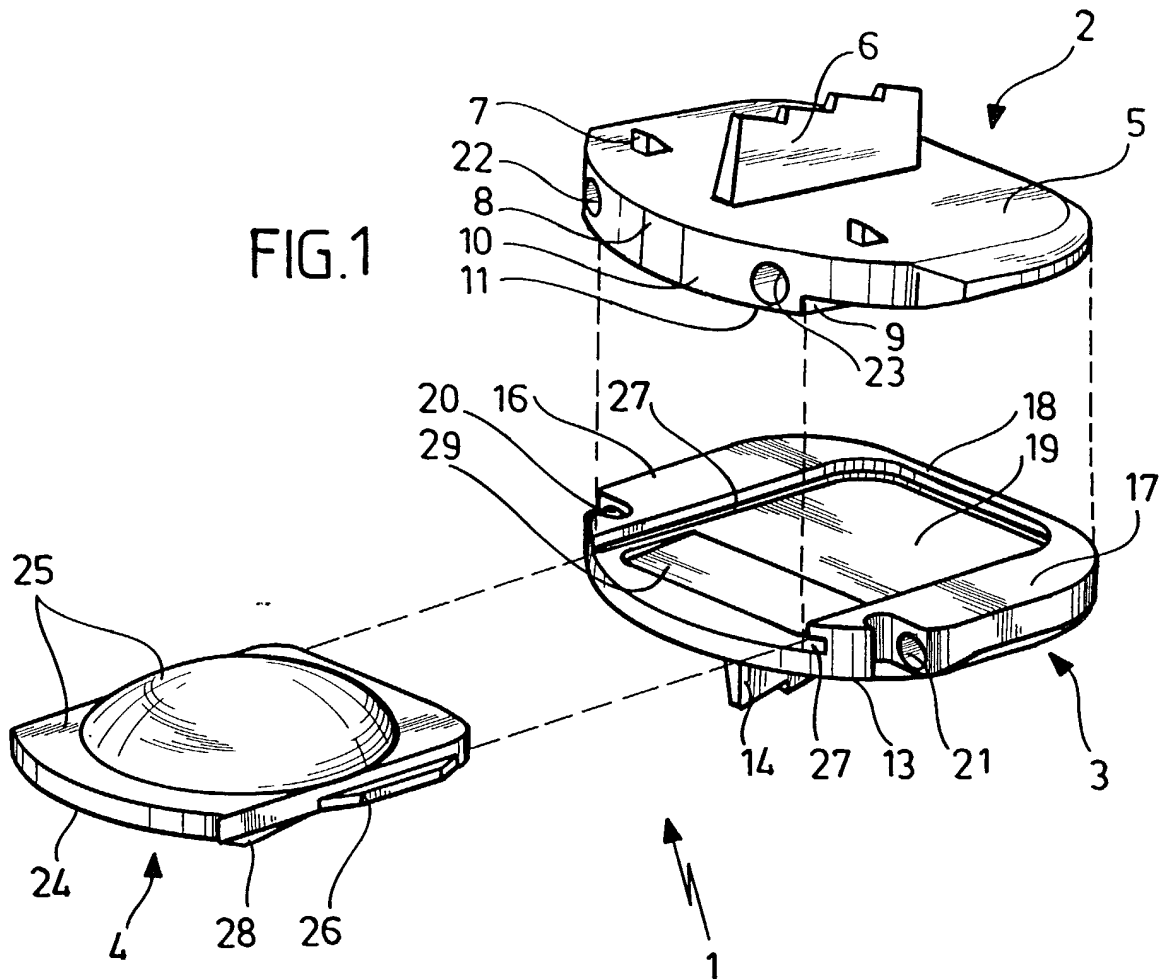
17. The implant of one of claims 11-16, characterized in that the pivot insert (4) substantially completely fills up the central receptacle (19) and with its spherical support face (25) protrudes from the receptacle (19).

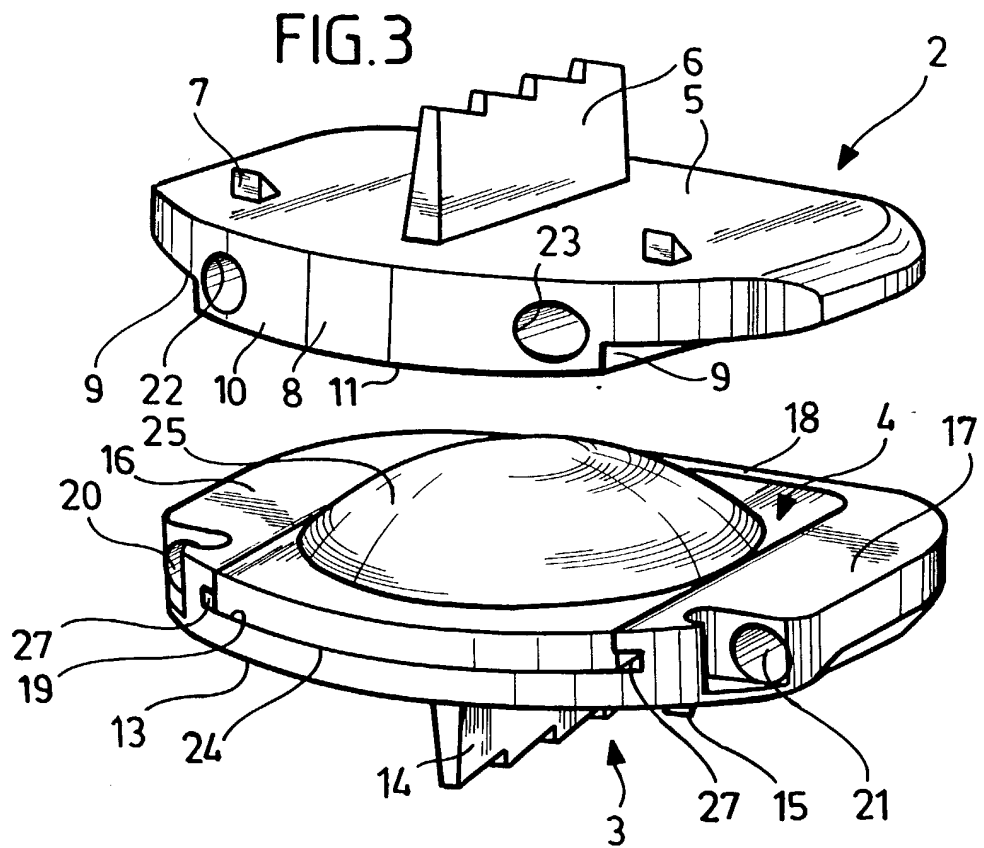
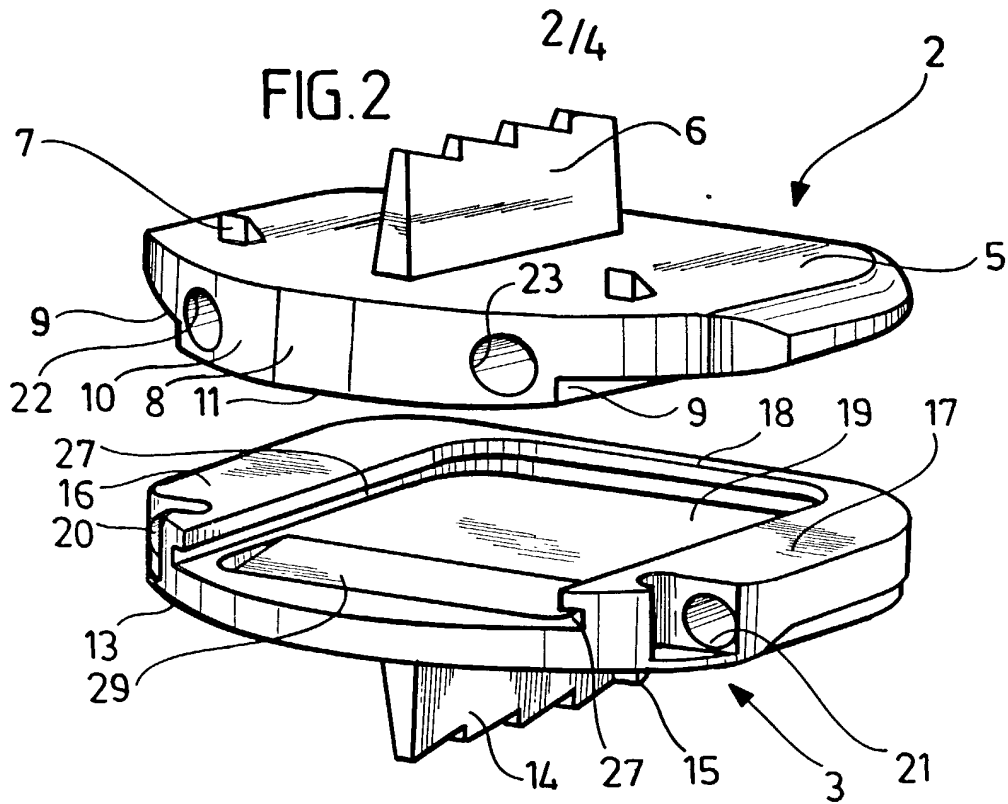
ABSTRACT

In an intervertebral implant, having an upper part that has a support face for a vertebra and a lower part that has a support face for an adjacent vertebra, on each of which parts engagement elements, which are accessible from one side of the intervertebral implant, for a manipulation instrument are disposed, in order to minimize the structural height of the intervertebral implant upon insertion into an intervertebral space, it is proposed that the upper part and lower part each have protrusions and recesses aimed at the respectively other part, which are offset laterally from one another in such a way that when the upper part has been brought close to the lower part they mesh with one another; and that the engagement elements on the upper part and on the lower part are each disposed in protrusions of these parts in such a way that the engagement elements of the upper part and lower part are located side by side and at least partly overlap in the direction of the height of the intervertebral implant.

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FIG.1





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FIG.4

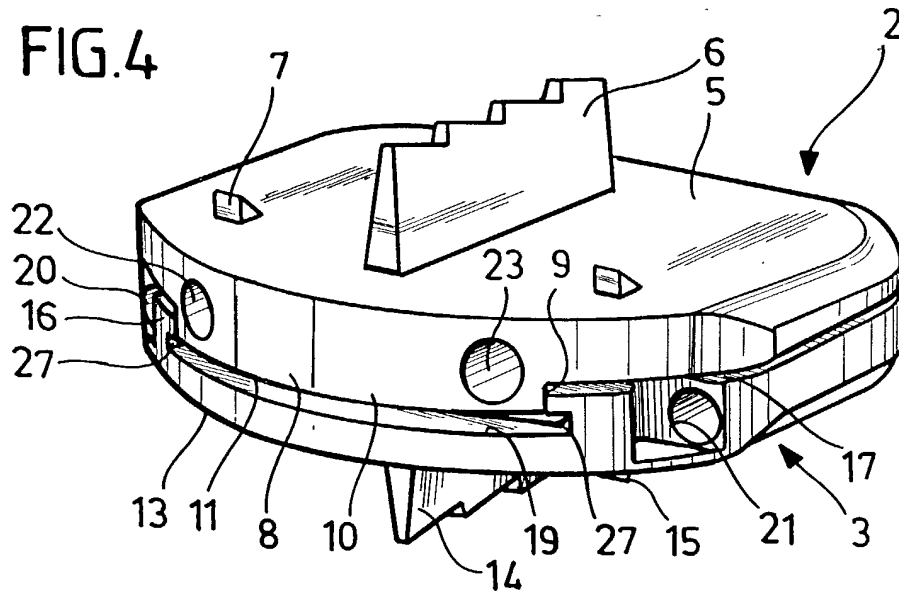
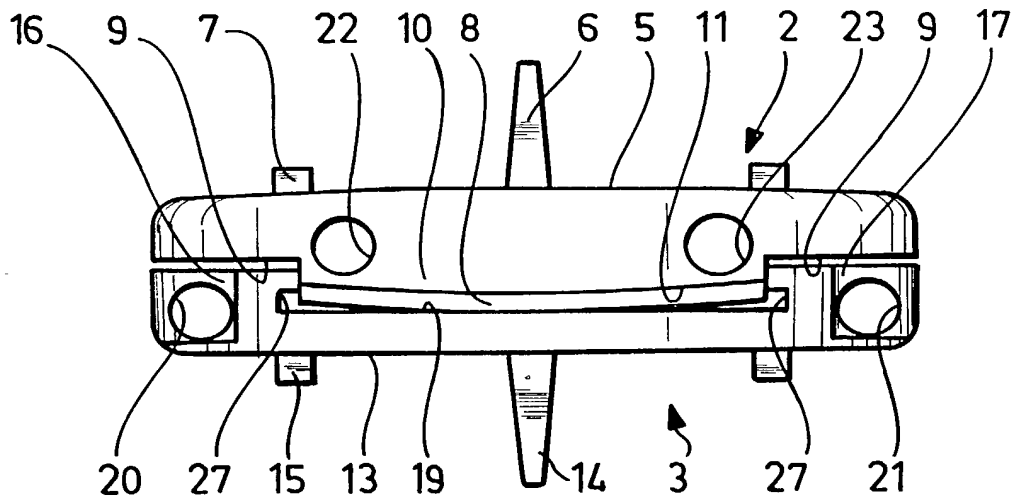


FIG.5



4/4



FIG.6

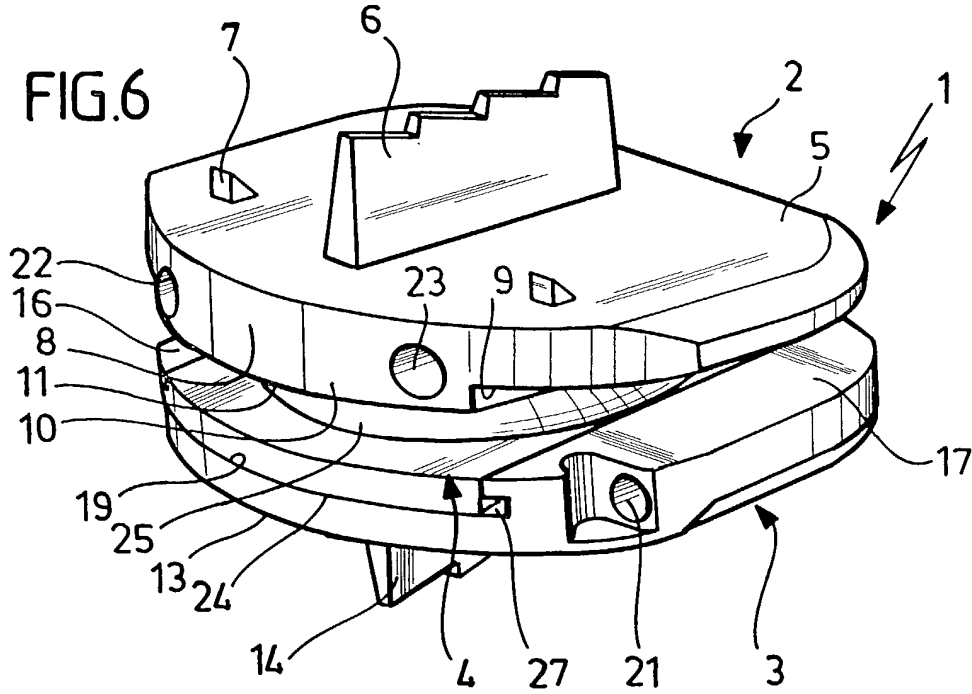
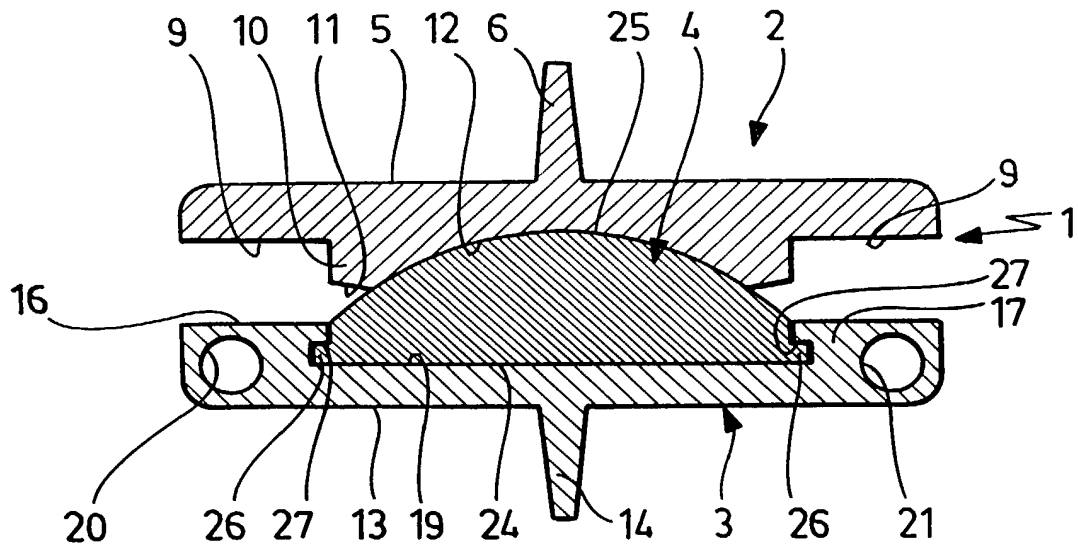


FIG.7



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| DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION | Docket No. | P06794US00/MP |
| | 1 st Inventor | MARNAY, et al |
| | COMPLETE IF KNOWN | |
| Declaration Submitted with Initial Filing | Serial No. | 10/018,402 |
| <input checked="" type="checkbox"/> Declaration Submitted after Initial Filing | Filing Date | December 19, 2001 |

As a below named inventor, I hereby declare that:

My residence, mailing address and citizenship are as stated below next to my name.

I believe I am the original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

INTERVERTEBRAL IMPLANT

the specification of which:

is attached hereto

OR

☒ was filed on July 2, 1999 as PCT/EP99/04628 (nationalized on December 19, 2001 as U.S. Ser. No. 10/018,402)
and (if applicable) was amended on .

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim FOREIGN PRIORITY benefits under 35 USC 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's certificate(s), or 385(a) of any PCT internat'l application which designated at least one country other than the US, listed below and have also identified below by checking the box, any foreign application for patent, inventor's certificate(s), or any PCT internat'l application having a filing date before that of the application on which priority is claimed. (ADDITIONAL APPLICATIONS IDENTIFIED ON ADDITIONAL INFORMATION SHEET)

| Prior Foreign Appl. No. | Country | Day/Month/Year Filed | Priority Not Claimed |
|-------------------------|---------|----------------------|----------------------|
| | | | |

As a named inventor, I hereby appoint the registered practitioners of **LARSON & TAYLOR, PLC** associated with Customer Number 000881 to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith. Direct all correspondence to that Customer Number.Direct all telephone calls to Marvin Petry
at TEL (703) 739-4900 (Fax: 703-739-9577) e-mail:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. (ADDITIONAL INVENTORS IDENTIFIED ON ADDITIONAL INFORMATION SHEET)

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| | 1 st Inventor | MARNAY, et al |
| | COMPLETE IF KNOWN | |
| | Serial No. | 10/018,402 |
| Declaration Submitted with Initial Filing | Filing Date | December 19, 2001 |
| <input checked="" type="checkbox"/> Declaration Submitted after Initial Filing | | |

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INTERVERTEBRAL IMPLANT

the specification of which:

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| SIGN AND DATE HERE | | Inventor's Signature | Date |